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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/530,370	07/06/2000	Robert C. Fahey	UCSD1130-1	6677

7590

04/04/2002

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EXAMINER

SWARTZ, RODNEY P

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 04/04/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/530,370

Applicant(s)

FAHEY ET AL.

Examiner

Rodney P. Swartz, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) 12-39 and 43-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 40-42 and 46-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-50 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

1. Applicants' Response to Restriction Requirement, received 9 January 2002, paper #7, is acknowledged.

Applicants elect, with traverse, Invention I, claims 1-11, and 40-42, drawn to antibody, first method of use (identification of bacteria), and a kit.

The traversal is on the grounds that applicants do not claim a "product", i.e., an antibody, and that from the claim description the methods have in common detection of mycothiol or a precursor thereof using reagents. Thus, there would be no serious burden on the examiner to consider the asserted claims together in a single application. This is not found persuasive because claims 9-11 are drawn to a "product", i.e., an antibody which is utilized in the three patentably distinct methods inventions. Also, while the search for the inventions may overlap, the searches are not coextensive.

Therefore, the requirement is still deemed proper and is therefore made FINAL.

New claims 46-50 have been added.

Claims 12-39 and 43-45 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

2. Claims 1-11, 40-42, and 46-50 are under consideration.

Drawings

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3. This application has been filed with drawings which are acceptable for examination purposes only. The drawings are objected to for the reasons set forth on the attached form PTO-948.

Specification

4. The disclosure is objected to because of the following: Example 7, page 44 states that the results of an ELISA protocol for testing the specificity of an antibody is in Figure 3. However, Figure 3 is a membrane blot detection of MSH in various bacterial colonies. Appropriate correction is required, and it is suggested that all references to Figures in the remaining specification correspond to the actual Figures.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-11, 40-42, and 46-50 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for antibody which binds to whole MSH and detects actinomycetes, does not reasonably provide enablement for antibody which binds to all precursors of MSH. The specification does not enable any person skilled in the art to which it



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pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. .

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the invention - methods and products using antibody which detects mycothiol or a precursor thereof.

While mycothiol and precursors are known in the art, the specification provides examples and guidance for antibodies which bind to whole MSH, but Figure 4 which shows the results of antibody reaction with only a few precursors indicates that the antibody does not recognize precursors except perhaps NAcCysGlcN.

Therefore, the scope of the instant claims, i.e., detection of a member of actinomycetes using antibodies which bind to a precursor of MSH, and said antibodies for such detection, constitutes merely an invitation to experiment without a reasonable expectation of success.

Claim Rejections - 35 USC § 102

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7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-3, 7, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Newton et al (*Journal of Bacteriology*, 178(7):1990-1995, April 1996).

The instant claims are drawn to a method of detecting a member of the taxa actinomycetes comprising incubating a sample with a reagent that detects mycothiol or a precursor thereof, detecting said reaction, wherein detection of said reaction is indicative of the presence of a member of the taxa actinomycetes.

Newton et al teach a method of detecting and quantifying mycothiol in a sample by incubating a reagent (mBBR) for a time sufficient for said reagent to react with mycothiol, and detecting said reaction of said reagent with mycothiol (section **Cell extraction for thiol analysis**, page 1992). The detection of the mycothiol is indicative of the presence of a member of the taxa actinomycetes, specifically mycobacteria. The samples used for detection of mycothiol were obtained as patient isolates from various university medical centers (section **Bacterial strains and culture conditions**, page 1991).

Claim Rejections - 35 USC § 103

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9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 40 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Newton et al (*Journal of Bacteriology*, 178(7):1990-1995, April 1996).

The instant claims are drawn to a kit comprising reagents for detection of mycothiol or a precursor thereof.

Newton et al teach a method of detecting and quantifying mycothiol in a sample by incubating a reagent (mBBR) for a time sufficient for said reagent to react with mycothiol, and detecting said reaction of said reagent with mycothiol (section **Cell extraction for thiol analysis**, page 1992). The detection of the mycothiol is indicative of the presence of a member of the taxa actinomycetes, specifically mycobacteria. The samples used for detection of mycothiol were obtained as patient isolates from various university medical centers (section **Bacterial strains and culture conditions**, page 1991). .

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to package the reagents utilized in the methods of Newton et al into a convenient kit form.

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Claim Objections

11. Claim 2 is objected to because of the following informality: "actinomyces" should be "actinomycetes". Appropriate correction is required.


Conclusion

12. Claims 1-11, 40-42, and 46-50 are rejected.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (703)308-3909. The facsimile telephone number for the Art Unit Group is (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-0196.


RODNEY P. SWARTZ, PH.D.
PRIMARY EXAMINER
Art Unit 1645

April 3, 2002